Pending Claims as of June 2003

18. A thrombin preparation comprising thrombin and a noncovalently binding inhibitor of thrombin activity as stabilizer, wherein the thrombin preparation is pharmaceutically acceptable.

19. (Amended) The thrombin preparation as claimed in claim 18, which additionally comprises a soluble calcium salt, sodium chloride as stabilizer, a buffer substance, and further comprises at least one of

a sugar,

a sugar alcohol,

an amino acid,

a salt of a mono- or polycarboxylic acid, or

a salt of a mono- or polyhydroxycarboxylic acid,

wherein the thrombin preparation is stable in the liquid state.

20. A process for producing a thrombin preparation, comprising a prothrombin obtained from plasma or a plasma fraction, wherein, following activation of the prothrombin to thrombin, and optionally further processing steps, the thrombin is purified by hydrophobic interaction chromatography.

21. The process as claimed in claim 20, wherein the prothrombin employed for activation to thrombin is subjected to inactivation or reduction of viruses during its production.

22. The process as claimed in claim 20, wherein the thrombin is subjected to inactivation or reduction of viruses before or after hydrophobic interaction chromatography.

23. The process as claimed in claim 20, additionally comprising cation exchange chromatography carried out before or after the hydrophobic interaction chromatography.

24. The process as claimed in claim 20, wherein the thrombin preparation is adjusted to a pH of from 5.0 to 8.0.

25. The process as claimed in claim 20, wherein a soluble calcium salt and sodium chloride as stabilizers, a buffer substance, and at least one of

a sugar,
a sugar alcohol,
an amino acid,
a salt of a mono- or polycarboxylic acid, or

are added to the thrombin preparation.

26. The process as claimed in claim 20, wherein a noncovalently binding inhibitor of thrombin activity is added as a stabilizer.

27. The process as claimed in claim 26, wherein the noncovalently binding inhibitor of thrombin activity is benzamidine or p-aminobenzamidine.

28. The process as claimed in claim 20, wherein a gel with coupled hydrophobic radicals is employed as absorbent for the hydrophobic interaction chromatography.

29. The process as claimed in claim 28, wherein the hydrophobic radicals of the gel employed as absorbent are phenyl radicals or ligands of similar hydrophobicity.

30. The process as claimed in claim 20, additionally comprising filtration of the thrombin preparation through a membrane with a suitable pore size to remove viruses.

31. A thrombin preparation, which is obtainable by the process of claim 20.

32. A method of using the thrombin preparation of claim 18 as a hemostatic, a constituent of a hemostatic or as a constituent of tissue glue.

33. A method of using the thrombin preparation of claim 19 as a hemostatic, a constituent of a hemostatic or as a constituent of tissue glue.

34. A method of using the thrombin preparation of claim 31 as a hemostatic, a constituent of a hemostatic or as a constituent of tissue glue.

35. The thrombin preparation of claim 18 wherein the noncovalentiy binding inhibitor of thrombin activity is benzamidine.

36. The thrombin preparation of claim 18 wherein the noncovalently binding inhibitor of thrombin activity is p-aminobenzamidine.

37. The thrombin preparation of claim 18 wherein, after 12 months of storage at 20-25 °C, the thrombin maintains at least 70% of its original level of activity.

38. The thrombin preparation of claim 18 wherein the thrombin preparation has a pH of from 5.0 to 8.0